UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA *ex rel*. KEVIN N. COLQUITT, Plaintiff, v. ABBOTT LABORATORIES, et al., Defendants.	Civ. Action No. 3:06-cv-1769-M (ECF)

RELATOR'S BRIEF IN SUPPORT OF MOTION FOR NEW TRIAL

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RELATOR'S BRIEF IN SUPPORT OF MOTION FOR NEW TRIAL

Subject to and without waiving any of his arguments and objections, Relator Kevin N. Colquitt requests that the Court vacate the April 8, 2016 Final Judgment and order a new trial in the above-captioned matter.

I. INTRODUCTION

This is a False Claims Act case brought by Relator against Defendants Abbott Laboratories and Abbott Vascular Solutions, Inc. (collectively, "Defendants"). On March 22, 2016, this Court commenced a jury trial in this matter. On April 7, 2016, the jury returned a verdict in favor of the Defendants. On April 8, 2016, the Court then entered a Final Judgment on the jury verdict in favor of Defendants. Relator now files this motion asking the Court to vacate the Final Judgment and order a new trial. The grounds for such relief under Fed. R. Civ. P. 59 are set forth herein.

II. SUMMARY OF ISSUES PRESENTED BY GROUNDS FOR NEW TRIAL

(1) Should the Court grant Relator a new trial because of erroneous evidentiary rulings?

(2) Should the Court grant a new trial because of improper jury arguments made by Defendants' counsel?

(3) Should the Court grant a new trial because of erroneous instructions included in or omitted from the jury charge?

(4) Should the Court grant Relator a new trial because the conduct of the trial disadvantaged Relator in such a way that he did not have a reasonable opportunity to make a full and fair presentation of his case to the jury?

(5) Should the Court grant Relator a new trial in the interest of justice?

(6) Should the Court grant Relator a new trial because of erroneous adverse rulings addressed in previous papers, hearing, and trial, including but not limited to the adverse pretrial rulings dismissing Relator's fraudulent inducement liability theory and the claims falling outside the time period of his employment, and the adverse directed verdict against Relator's false statement claim?

III. STANDARD OF REVIEW

A new trial is appropriate under Federal Rules of Civil Procedure 59 and 61 when justice requires and a party's substantial rights were affected. Fed. R. Civ. P. 59, 61. A district court determines whether to grant a new trial "based on its appraisal of the fairness of the trial and the reliability of the jury's verdict." *Smith v. Transworld Drilling Co.*, 773 F.2d 610, 612-13 (5th Cir. 1985); *see also* Fed. R. Civ. P. 59 (a)-(d). Although Federal Rule of Civil Procedure 59 does not limit the grounds on which a new trial may be granted, a new trial is proper, "for example, if the district court finds the verdict is against the weight of the evidence, the damages awarded are excessive, the trial was unfair, or prejudicial error was committed in its course." *Smith*, 773 F.2d at 613; *Scott v. Monsanto Co.*, 868 F.2d 786, 789 (5th Cir. 1989). The court can also grant a new trial when necessary to prevent injustice. *See, e.g., Gov't Fin. Servs. One L.P. v. Peyton Place, Inc.*, 62 F.3d 767, 774 (5th Cir. 1995).

IV. ARGUMENT AND AUTHORITIES

Justice requires a new trial for Relator for all of the reasons discussed below. Further, as discussed below, Relator's substantial rights were affected.

A. RELATOR IS ENTITLED TO A NEW TRIAL BECAUSE OF ERRONEOUS EVIDENTIARY RULINGS

"Generally, a trial court has broad discretion to conduct the trial in an efficient and orderly manner in the admission or exclusion of evidence." *Gates v. Shell Oil*, 812 F.2d 1509, 1512 (5th Cir. 1987). However, the Court may grant a new trial based on the exclusion or admission of evidence if the improper rulings affected a party's substantial right. *Munn v. Algee*, 924 F.2d 568, 571 n.2, 573 (5th Cir. 1991); *Gates*, 812 F.2d at 1512. The following evidentiary rulings affected Relator's substantial rights and created harmful error, entitling Relator to a new trial.

1. Exclusion of Evidence that Defendants Misled the Government and that the Government Disapproved of Defendants' Conduct

Defendants repeatedly emphasized to the jury their claim that the FDA not only knew of,

but "blessed," Defendants' conduct with regards to their promotion of their biliary stents for vascular procedures. For example:

- Defendants introduced repeated testimony that they had numerous discussions with the FDA regarding their biliary stents and that the FDA was even in attendance at the VIVA conference, creating the impression that the FDA knew of and blessed Defendants' conduct. (*See, e.g.*, 03/29/16 Tr. at 149:10-13; 04/04/16 Tr. at 81:19-82:7, 83:21-84:7, 84:25-85:3, 85:6-9, 86:14-18, 89:2-4, 89:12-13, 91:24-25, 93:21-25, 159:5-6, 159:18-22, 164:4-8, 180:11-14, 185:13-18).

- Defendants showed the jury a demonstrative exhibit which stated that a device that gets marketing clearance through the 510(k) process and a device that has PMA approval have both been "blessed" by the FDA. (DDX 63).

- Defendants' counsel stated in his opening statement that "[t]he FDA positively understands this is happening. . . ." and that the "FDA floods the market with biliary stents, okay? They really do. They know this is happening. They know that the only way these patients can get care is with biliary stents." (03/22/16 Tr. at 113:6-13, 135:20-23). Then in closing arguments, Defendants' counsel argued that "hundreds of biliary stents were approved by the FDA with full belief that were being used off-label." (04/07/2016 Tr. at 116:25-117:1).

- Defendants also introduced evidence that Medicare paid for biliary stents in vascular procedures after Colquitt blew the whistle in September 2006. (03/28/2016 Tr. at 286:15-287:18).

- Defendants further argued in closing that because CMS continued to pay for vascular stenting procedures utilizing biliary stents after Colquitt blew the whistle, Abbott's biliary stents were eligible for Medicare coverage. (04/06/2016 Tr. at 100:20-101:18).

To rebut this stream of evidence and argument, Relator sought to introduce evidence that the FDA did not approve of Defendants' promotion of the Absolute biliary stent. For instance, Relator sought to introduce a December 19, 2007 Warning Letter from the FDA to Chuck Foltz, President of Abbott Vascular Solutions, informing Defendants their promotion and marketing of the Absolute biliary stent for vascular use rendered the stent "adulterated" and "misbranded." (PX-462). The FDA warned Defendants that they had to "immediately cease" their off-label promotion of the stent and take "prompt action" to correct these "deviations" from federal regulations. *Id.*

Relator also sought to introduce a letter from Mr. Foltz to the FDA, which detailed

Defendants' remediation plan, including that sales personnel should recommend that biliary cleared devices not be used in the vasculature and highlight the serious adverse events when biliary cleared products are used in the vasculature. (PX-418). Defendants objected to both of these exhibits as "irrelevant and prejudicial," and the Court sustained Defendants' objections. (03/31/2016 Tr. at 152:2-10).

The Court's ruling excluding Relator's FDA evidence left him unable to rebut Defendants' arguments and evidence on this issue. Defendant's Medicare expert testified that Medicare relies on FDA's determination of safety and effectiveness. (04/05/2016 Tr. at 237:6-18). Further, Bagley stated that:

> [Medicare] rel[ies] on the fact that it's legally marketed. Now, beyond that, Medicare has to make their determination based on the fact that it's legally marketed, that the FDA is — is looking over the safety, and they can then determine the medical necessity or whether it's reasonable and necessary.

(*Id*. at 237:23-238:6). In addition, the Court instructed the jury that action by the FDA, while not binding, is something Medicare may consider. (Dkt. 820 (Court's Charge) at 8). Yet, the Court's instruction did not have the persuasive reach that accompanies the actual admission of evidence. The instruction was a denial of Relator's opportunity to support his theory of the case with actual evidence. There is a vast difference between an unsupported instruction and actual evidence supporting a theory. By not allowing Relator to introduce the FDA evidence, the Defendants were permitted to give the jury the impression that the FDA tacitly or impliedly approved of, or was simply neutral towards, Defendants' conduct when, in fact, the FDA expressly took action against Defendants. According to Defendants' own expert, this issue is of utmost importance as Medicare coverage is predicated on whether a device is legally marketed and whether a device is safe, both of which Medicare relies on the FDA to determine. The jury should have been permitted to weigh evidence that the FDA did not believe Defendants' Absolute stent was legally marketed and that

the Defendants made misrepresentations that inhibited the FDA's evaluation of whether Defendants' other biliary stents were legally marketed and whether those stents were safe for the Defendants' intended use. These misrepresentations occurred during same time frame that the Medicare payments for vascular procedures using biliary stents occurred, which Defendants' counsel argued was dispositive evidence that Abbott's biliary stents were eligible for Medicare coverage.[1]

In sum, the jury was provided an incorrect impression that the FDA was aware of and approved of Defendants' promotion of their biliary stents for vascular procedures, leading to undue confusion for the jury and a miscarriage of justice in this case. This impression and the harm of allowing Defendants' evidence while excluding Relator's were not cured by the Court's instruction to the jury that "although FDA representatives attended the various conferences at which Guidant was present, the FDA did not bless or approve in any way the marketing or promotion by Guidant of biliary stents for use in the vasculature."

The exclusion of the FDA-related evidence affected Relator's substantial rights. For the foregoing reasons, and in the interest of justice, Relator is entitled to a new trial.

2. Exclusion of Ancure Evidence

In addition to its biliary stents, Guidant sold a stent-graft device called the Ancure. In 2002, the division that sold the Ancure device ("Endovascular Solutions, Inc.") merged with the Guidant division that sold biliary stents. (3/24/2016 Tr. at 263:11-12). In 2003, Endovascular Solutions, Inc. plead guilty to ten felony charges: one count for making false statements to the FDA and nine counts related to Guidant's failure to report adverse events associated with the Ancure device. (PX 783 at 2). The allegations included failure to report to the FDA deployment problems that required

[1] These errors and resulting harm were further compounded by the omission of an instruction in the Court's charge that government payment of claims is not a defense, which is discussed further in Sections IV(C)(2)(c) & (d), below.

physicians to break the handle of the device in order to facilitate full deployment. (*See id*. at 5-10).

During opening statements, Defendants' counsel stated that Guidant was "a great, great company" and "a responsible company." (3/22/2016 Tr. at 138:9, 142:16). Counsel further represented that Guidant gave the "FDA every single piece of data that was relevant to [adverse recalls of their biliary stents] and that the law required." (*Id.* at 143:12-14.) Afterward, Relator sought unsuccessfully several times to introduce the Ancure plea into evidence. For example:

- Relator's counsel requested leave to introduce the Ancure plea in Relator's case-in-chief in order to rebut Abbott's opening statements, but that request was denied. (3/22/2016 Tr. at 183:1-21).
- Relator renewed his request for admission by letter brief (Dkt. 761), but the renewed request was denied (3/23/2016 Tr. at 208:7-14).
- Relator proffered the Ancure plea and excerpted testimony from the Rapoza, Huss, and Neupert depositions. (Dkt. 768 (Relator's Notice of Proffer of Evidence Regarding Ancure)). Though timely, the proffered evidence was not admitted. (3/29/2016 Tr. at 10:1-12).

Relator's inability to impeach Defendants' witnesses and to rebut arguments with Guidant's guilty plea to ten felonies in 2004 related to Guidant's failure to report adverse events to the FDA allowed Defendants to create the misimpression that Guidant was a "responsible company" complying with FDA reporting requirements and affected Relator's substantial right to a fair trial. The error and harm in excluding the evidence was compounded when Mr. Rapoza testified at trial that, from 2004 to 2006, Defendants complied with FDA's reporting requirements and this reporting data demonstrated only a remote chance of injury associated with Guidant's biliary stents. (*See, e.g.*, 04/04/2016 Tr. at 137:23-138:4, 140:10-11, 141:1-2, 146:25-147:3, 148:3-5, 149:4-10, 151:18-152:2, 152:4-10, 154:8-13, 163:7-18, 163:20-164:3).

This evidentiary error affected Relator's substantial rights and, in the interest of justice, requires a new trial.

B. RELATOR IS ENTITLED TO A NEW TRIAL BECAUSE OF IMPROPER JURY

ARGUMENT BY DEFENDANTS' COUNSEL

Improper jury arguments for which the Court may grant a new trial include those that influence the jury by passion or prejudice, misstate the law, or misrepresent the facts. *See, e.g., Whitehead v. Food Max of Miss., Inc.*, 163 F.3d, 265, 276-78, 282 (5th Cir. 1998) (finding that counsel's community conscience and Golden Rule arguments, among others, meant to inflame the jury's passions and warranted a new trial); *Westbrook v. Gen. Tire & Rubber Co*., 754 F.2d 1233, 1238-41 (5th Cir. 1985) (finding that counsel's community conscience argument was improper and prejudicial); *Edwards v. Sears, Roebuck & Co*., 512 F.2d 276, 284-85 (5th Cir. 1975) (finding that closing argument including facts not in evidence and other pleas to the jury's passions were prejudicial and substantially affected the trial's fairness). Unobjected-to trial errors may still be reviewed as plain error if the errors are "both obvious and substantial" or "otherwise seriously affect the fairness, integrity, or public reputation of judicial proceedings." *Rojas v. Richardson*, 703 F.2d 186, 190 (5th Cir. 1983), *on reh'g*, 713 F.2d 116 (5th Cir 1983) (citations omitted).

In deciding a challenge that improper arguments were made during closing, the Court reviews "the entire argument . . . within the context of the court's rulings on objections, the jury charge, and any corrective measures applied by the trial court." *Learmonth v. Sears, Roebuck & Co.*, 631 F.4d 724, 731 (5th Cir. 2011) (quoting *Westbrook*, 754 F.2d at 1238) (internal quotation marks omitted, alteration in original). The Court need not find that each statement, taken individually, was so improper as to warrant a new trial, but only that, taken as a whole, Defendants' improper comments prejudiced the jury's findings. *See Whitehead*, 163 F.3d at 278.

Jury awards influenced by passion and prejudice are the antithesis of a fair trial. *Whitehead*, 163 F.3d at 276. This hotly contested case—in which Defendants pursued themes that, among other things, a verdict for Relator would contravene the FDA's "blessing," impermissibly interfere with doctors' independent medical judgment, and deprive senior citizens of the "best

possible" medical care—was fertile ground for such bias. *See id.* In such cases, "counsel must be unusually vigilant and take the greatest care to avoid and prevent such appeals [to emotion], in order to keep the verdict from being infected by passion and prejudice." *Whitehead*, 163 F.3d at 276.

Relator requests that the Court vacate the Final Judgment and order a new trial based on the following improper jury arguments made by Defendants' counsel during their closing argument. Whether examined individually or considered together, these improper arguments created harmful error. The take-nothing verdict and the precipitous haste in which the jury reached it are but two of the signposts that the jury was influenced by the prejudicial arguments, which encouraged them to decide the case on the basis of emotion and bias, and distracted them from their duty to decide the case based on the extensive testimony and evidence presented during the three-week trial.

1. Golden Rule Argument

Invocation of the Golden Rule "[is] improper because it encourages the jury to depart from neutrality and to decide the case on the basis of personal interest and bias rather than the evidence." *Brown v. Parker Drilling Offshore Corp.*, 410 F.3d 166, 180 (5th Cir. 2005) (quoting *Ivy v. Sec. Barge Lines, Inc.*, 585 F.2d 732, 741 (5th Cir.1978)) (quotation marks omitted, alteration in original). "Even if counsel does not explicitly invoke the Golden Rule but merely invites the jury to place themselves in the position of the [litigant], the result is effectively the same and the risk of taint is no different." *Id.* (citing *Whitehead*, 163 F.3d at 278).

In closing arguments, Defendants' counsel repeatedly bade jurors to put themselves into the Defendants' shoes. For example:

- "But here's the point. **Your mother** on the table getting a stent procedure and these doctors are telling you on-label stents, obsolete -- the problems I have just gone

through. The doctor said, I recommend a biliary stent. **You want your doctor to make that choice.** You want your doctor, like Dr. Laird and Dr. Krol, Dr. Ansel, all of these doctors that you saw, you want them to make that choice, and they chose biliary stents." (04/07/2016 Tr. at 104:11-13 (emphasis added)).

- "And when it's on the table, you want that doctor choosing the device that in their heart of hearts they are going to choose upon **the Golden Rule**. Dr. Burket said**, if I'm on the table or my family member is on the table**, what device do I want to use? The best possible device to get the best possible treatment. Every single time would be a biliary stent. And these folks used the Guidant biliary stent hundreds of times." (04/07/2016 Tr. at 133:21-134:3 (emphasis added)).

Defendants' arguments asked jurors to decide this case by imagining themselves or their family members in the position of a patient in need of a vascular stenting procedure. Defendants' arguments were particularly inflammatory to this jury because one of its member's sister had an unsuccessful carotid stenting procedure, which was discussed in front of the entire panel during voir dire. (03/15/16 Tr. at 121:13-21). In fact, the juror's sister died during that procedure. (*Id*. at 151:17-152:1). Additionally, due to exclusion of Relator's evidence that the FDA did not approve of Defendants' promotion of their stents for use in vascular procedures, Defendants were also able to argue in closing that the FDA was fully aware of and even "blessed" off-label use of Defendants' stents, giving jurors the misimpression that there was nothing wrong with using these stents in vascular procedures and that they should want doctors to continue using them off-label, and for Medicare to continuing paying for their use. (*E.g.*, 04/06/2016 Tr. at 100:20-101:18). Defendants' closing arguments improperly influenced the jury to decide this case based on passion, personal interest, and a misrepresentation of the facts. These arguments seriously affected the fairness, integrity, or public reputation of judicial proceedings and amount to obvious and substantial error.

2. Community Conscience Argument

In closing arguments, Defendants' counsel repeatedly urged the jury to be the conscience of the community to ensure seniors continue to receive medical care. For example:

- "They're saying if it's a biliary stent and therefore has no clinical trials to support it, therefore, Medicare shouldn't pay for it and doctors shouldn't make that available to Medicare patients. Thinking about how stunning that would be for all of these patients. . . . Stenting wouldn't have been available for most of these people." (04/07/2016 Tr. at 89:3-12).

- "Medicare patients would be decimated if suddenly off-label uses were not paid for by Medicare; certainly paid for by private insurance." (*Id.* at 104:11-13).

- "You heard Dr. Laird yesterday. He choked up when he was talking about the almond farmer. He treated that man with a biliary stent and changed his life." (*Id.* at 87:5-7).

- "In this instance, the case ought to be about—the focus ought to be about and—what is best for patients." (*Id.* at 85:10-11).

- "Burket. It was pretty clear to me -- he was the gentleman that came from Ohio. Understanding that their argument would exclude his ability to use off-label stents on his – he's not being paid by either side. He came here to testify to you. He felt strongly about that. He wants to make sure this case doesn't go south, so he continues to have the best tools available for his patients." (*Id.* at 113:14-20).

- "If Mr. Hamilton and Mr. Colquitt were right, that option would have been off the table, except for the independently wealthy who could pay for these stenting procedures by themselves." (*Id.* at 120:1-4).

Such "conscience of the community" arguments, "intended to evoke a sense of community loyalty, duty and expectation," serve no proper purpose and can result in substantial injustice. *Westbrook*, 754 F.2d at 1238-39. They distract the jury from its sworn duty to reach a fair, honest, and just verdict according to the facts and evidence presented at trial. *Whitehead*, 163 F.3d at 277.

Defendants' counsel's improper closing arguments exacerbated the harm from the erroneous exclusion of Relator's FDA evidence and the failure to instruct the jury in the Court's charge on the proper definition of "reasonable and necessary." Defendants were able to misrepresent to the jury that the use of their stents in vascular procedures was not only blessed and approved by the FDA, but was also the gold standard selection for vascular procedures. Defendants' "community conscience" arguments told the jury that it had a duty to make sure that seniors can continue to receive this gold standard care and that a verdict for Relator would leave

countless seniors without access to essential medical care. Defendants' arguments had no proper purpose. Moreover, they put Relator in the unfair position of having to argue against the community conscience without the ability to introduce evidence to rebut it. Defendants' improper arguments affected Relator's substantive rights and resulted in substantial injustice to Relator. These arguments seriously affected the fairness, integrity, or public reputation of judicial proceedings and amount to obvious and substantial error.

3. Misrepresentations of Evidence and Facts not in Evidence

Defendants' counsel made several arguments in closing that misrepresented the evidence or asserted facts that were not in evidence. These arguments, taken individually or as a whole, were prejudicial and substantially affected the fairness of the trial.

For example, Defendants' counsel gave the following narrative in closing arguments:

> Dr. Ansel, he talked about the grandmother who couldn't get to the mailbox. She was depressed, lethargic. She came in two months later, a different woman completely. Suddenly she's able to go to the store, to church, to social events and the local senior center, and she's a different person.
> How was she treated? Biliary stents; no clinical trial. Medicare paid. It knowingly did the right thing, knowing that these Medicare patients, seniors and disabled, are getting the care that they needed. (04/07/16 Tr. at 87:14-23).

Despite Defendants' assertion, the evidence actually showed that some other biliary stents, including the most popular biliary stent used for vascular procedures, did complete clinical trials. Defendants' counsel even acknowledged, in the direct examination of John Laird, that "[t]he S.M.A.R.T. stent received its indication in '03, but hit the – didn't hit the marketplace with that indication until '06." (04/06/16 Tr. at 66:22-24). Dr. Laird testified that he was the "site principal investigator" for the clinical trial that led to the S.M.A.R.T. stent's indication. (*Id.* at 67:17-20).

Further, there is no evidence in the record that Medicare paid for the procedure narrated by Defendants' counsel in closing argument. (*See* 03/29/16 Tr. at 114:12-115:18 (Dr. Ansel's

testifying about the grandmother's case but making no mention of Medicare reimbursement)). And even if Medicare did pay for this procedure, there is no evidence that Medicare knew that this grandmother received a biliary stent and that it then knowingly paid for it. Defendants' counsel's closing argument misrepresented the facts in evidence and represented other facts as being in evidence, even though they were not.

Defendants' counsel also stated in closing that "[o]ff-label necessarily means there's no clinical trials." (04/07/16 Tr. at 104:3). Counsel went on to argue that if the jury gave a verdict for Relator, doctors would be unable to use devices in an off-label manner anymore because they have no clinical trials. (*Id.* at 104:1-13). These assertions are false and misleading. As explained above, some biliary stents, including the most popular biliary stent used for vascular procedures, did complete clinical trials. (04/06/16 Tr. at 66:22-24, 67:17-20). Defendants' counsel's argument to the contrary was misleading, prejudicial, and aimed at influencing the jury to make a decision based on passion rather than the evidence actually admitted in the case.

Defendants' counsel spun yet another interesting tale in closing arguments:

> You know what they do as a physician in New Jersey? You pick up the phone and you call your Medicare contractor and you say, hey, I'm using biliary stents because they're the best available stents. I need -- you were paying for them before. I need you to keep paying for them. And the Medicare contractors says, fine. That's the reality." (04/07/16 Tr. at 145:22-146:2).

However, there is no evidence in the record of any physician in New Jersey (or anywhere else) (1) making a phone call to a Medicare contractor; (2) stating that biliary stents are the best available stent; or (3) claiming that the local Medicare contractor was knowingly paying for the use of biliary stents; or that (4) the Medicare contractor agreed with the statements made during any such phone call. Defendants' counsel's story, which attempted to create fact from fiction, was improper and prejudicial to Relator. Defendants' misrepresentation of the evidence during closing

arguments seriously affected the fairness, integrity, or public reputation of judicial proceedings and amount to obvious and substantial error. *See Edwards*, 512 F.2d at 284-85 (finding that closing argument including facts not in evidence and other pleas to the jury's passions were prejudicial and substantially affected the trial's fairness).

4. Government's Lack of Involvement in the Case

In closing, Defendants' counsel also misrepresented the government's involvement in this case and argued that its supposed absence from the trial indicated that it did not agree with Relator's position. For example, in closing arguments, Defendants' counsel stated:

> There's 6,000 CMS patients -- 6,000 CMS employees. How many showed up here to say, yep, we were fooled. We never meant to pay for vascular stenting procedures with biliary stents. How many? None.
>
> They couldn't find a single witness at CMS to come here and say, yep, we were duped. Not one. This is extraordinary. I've been doing this a long time. I've never, ever seen a trial where a party was unable to find a witness who was there at the time, involved in the process, to support their position. But that's the situation we have here. (04/07/16 Tr. at 88:7-16).

Contrary to this argument, the purpose of *qui tam* lawsuits is to provide a means to discover and prosecute fraud against the government, because the government lacks the resources to prosecute every meritorious instance of fraud. *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 752 (5th Cir. 2001); *United States ex rel. Berge v. Bd. of Trustees of the Univ. of Ala.*, 104 F.3d 1453, 1458 (4th Cir. 1997), *cert denied*, 522 U.S. 916 (1997). Indeed, "the plain language of the Act clearly anticipates that even after the Attorney General has 'diligently' investigated a violation under 31 U.S.C.A. § 3729, the Government will not necessarily pursue all meritorious claims; otherwise there is little purpose to the *qui tam* provision permitting private attorneys general." *Berge*, 104 F.3d at 1458.

Relator filed a pretrial motion *in limine* to prevent irrelevant and prejudicial references to

the government's decision not to intervene in this case or its decision not to attend trial. (Dkt. 637 (Relator's Omnibus Motions *in Limine*) at 28-30); Defendants agreed to this *in limine*. (03/22/16 Tr. at 185:17-21). Nevertheless, Defendants still argued that the government failed to show up to support Relator at trial and that the jury should infer that the government failed to show up because it does not believe Defendants caused the submission of any false claims. Defendants' argument misrepresented the purpose and nature of a *qui tam* action and was highly prejudicial to Relator. These arguments seriously affected the fairness, integrity, or public reputation of judicial proceedings and amount to obvious and substantial error.

C. RELATOR IS ENTITLED TO A NEW TRIAL BECAUSE OF ERRONEOUS INSTRUCTIONS IN THE JURY CHARGE

Generally, "the district court has broad discretion to compose the instructions to the jury, as long as they are fundamentally accurate and not misleading." *Gates v. Shell Oil*, 812 F.2d 1509, 1512 (5th Cir. 1987). However, a new trial is required "if the trial judge's instructions to the jury, taken as a whole, give a misleading impression or inadequate understanding of the law and the issues to be resolved." *Bass v. Int'l Bhd. of Boilermakers*, 630 F.2d 1058, 1062 (5th Cir. 1980).

1. Instruction on Double Knowledge Requirement

The Court's jury charge required Relator to prove *both* that Defendants knowingly caused to be presented or submitted a claim for payment or approval *and* that Defendants knew the claim was false or fraudulent at the time the claim was made. (Court's Charge to the Jury at 5). Relator objected to the double knowledge requirement and asked for an instruction stating that "Defendants knowingly caused to be presented to an officer or employee of the United States a claim for payment or approval" and that "[t]he claim was false or fraudulent at the time it was made." (Dkt. 801 (Joint Summary of Proposed Jury Instructions and Questions) at 22; 04/06/2016 Tr. at 224:8-225:12). The Court overruled Relator's objections. (04/06/2016 Tr. at 240:4-5).

> In pertinent part, the False Statement section of the FCA imposes liability on a person who:
>
> ***knowingly*** makes, uses, or ***causes to be made*** or used, ***a false record or statement*** material to a false or fraudulent claim . . . .

31 U.S.C. § 3729(a)(1)(B) (emphasis added). The "knowingly" requirement appears only once. *Id.* The double knowledge requirement imposed by the Court's charge effectively rewrites Congress's language to provide that no violation occurs unless a person "knowingly makes, uses, or causes to be made or used, a ~~false~~ record or statement that the person knows to be false and that is material to a false or fraudulent claim."

This judicial revision is not only erroneous, but unnecessary because the statute provides the manner in which the "knowingly" applies. The False Claims Act defines "knowingly" to mean "that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information . . . ." 31 U.S.C. § 3729(b)(1)(A). Thus, the statute's plain language gives us the meaning of the standard that "a person or entity *knowingly* causes to be presented a false claim:" the person or entity causes to be presented a false claim *having actual knowledge of the information, acting in deliberate ignorance of the truth or falsity of the information, or acting in reckless disregard of the truth or falsity of the information.* 31 U.S.C. §§ 3729(a)(1)(B), 3729(b)(1)(A).

Defendants have not provided any authority, nor has Relator been able to locate any, supporting the imposition of a double knowledge standard. To the contrary, the Fifth Circuit has interpreted the False Claims Act according to its plain language, applying the "knowledge" standard as only one element (not two). *See, e.g., United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 259-60 (5th Cir. 2014) (setting forth FCA elements and discussing scienter, or knowledge, with regard to only one element); *United States ex rel. Longhi v. United States*, 575

F.3d 458, 467 (5th Cir. 2009) (setting forth "each element" of an FCA claim and stating the "scienter" requirement only once); *United States ex rel. Bennett v. Boston Sci. Corp.*, 2011 WL 1231577, at *14 (S.D. Tex. Mar. 31, 2011) (same). The double knowledge element in the Court's charge incorrectly instructed the jury on applicable law. The instruction improperly increased the burden of proof for Relator's false presentment claim. In addition, the instruction improperly nudged and tilted the jury toward a verdict against Relator.

Furthermore, the double knowledge instruction was confusing to the jury. The Court instructed the jury that Relator had to prove, among other things, that: (1) "Defendants *knowingly* caused" presentment of a false claim; and (2) "Defendants *knew* the claim was false or fraudulent" when made. (Dkt. 820 at 5 (emphasis added)). The jury was instructed as to the meaning of "knowingly," including the instruction that "[t]he term '*knowingly*' does not require any proof of specific intent to defraud," but "knowingly" was not equated with the term "knew." (*Id.* at 6 (emphasis added)). In addition to objecting to the instruction on the element of false presentment based on the incorrect double knowledge standard, Relator objected that the instruction was not consistent with the manner in which "knowingly" is defined and would confuse the jury. (04/06/16 Tr. at 224:8-225:12, 229:22-232:23). After this objection was overruled (*id.* at 240:4-5), Defendants' counsel told the jury in closing arguments that Relator had to prove that Defendants (specifically, their corporate representative Linda Dickes) had a "fraudulent intent to defraud Medicare." (04/07/16 Tr. 152:23-153:2, 156:15). Yet, the False Claims Act does not impose an "intent to defraud" element. 31 U.S.C. 3729(b)(1)(B); *Longhi*, 575 F.3d at 468; *United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 338 (5th Cir. 2008). Defendants' counsel's argument compounded the error and harm from the double knowledge instruction and led the jury into the confusion created by the inconsistent instructions, nudging them away from proper legal standards

and toward a take-nothing verdict. *See Houston v. Herring*, 562 F.2d 347, 349 (5th Cir. 1977).

The instructions regarding the double knowledge requirement prejudiced Relator's substantial rights and disserved justice. Relator is entitled to a new trial.

2. Omitted Instructions

Instructions that were requested by Relator but refused by the Court provide additional bases for a new trial. The court's charge must fairly and adequately cover all issues presented for the jury's determination. *McDonald v. Bennett*, 674 F.2d 1080, 1089 (5th Cir. 1982). The Court's failure to include an instruction to the jury on the standards the law requires them to apply to the evidence presented falls short of this standard. *See id.* A district court has a duty to define in its charge technical terms when their meaning must be understood by the jury in order to determine the issues submitted to it, unless the meaning is commonly understood by persons of ordinary intelligence. *Milwaukee Mechanics Ins. Co. v. Oliver*, 139 F.2d 405, 406 (5th Cir. 1943). Without the instructions necessary to inform the jury of the proper legal boundaries, other related instructions provide an incomplete (and therefore, incorrect) statement of the law. The following omitted instructions provide examples of the charge error, stated on the record at the charge conference, supporting a new trial in this case.

a. Omitted Definition of "Reasonable and Necessary"

The Court instructed the jury about the items or services being "reasonable and necessary:"

- "The private contractors are also bound by the terms of the Medicare statute in making reimbursement decisions. Among other things, the Medicare statute provides that 'no payment may be made . . . for any expenses incurred for items or services . . . [which] are not *reasonable and necessary* for the diagnosis of illness or injury. . . .'" (Dkt. 820 at 7 (italics added, ellipses and brackets in original));
- "The private Medicare contractors determine which items are *reasonable and necessary* for purposes of coverage under the statute." (*Id.* (italics added)); and
- "Local contractors with responsibility for the remaining states did not issue LCDs for non-coronary vascular stenting procedures. In such states, where no NCD or LCD for

> non-coronary vascular stenting procedures was in place, the local contractor made individual claims determinations, based on whether a particular claim meets the statutory requirement of being '*reasonable and necessary*.'" (*Id.* at 8 (italics added)).

Both sides requested that the Court instruct the jury on the legal definition of "reasonable and necessary." (Dkt. 801 at 52; 04/06/2016 Tr. at 234:9-235:4, 245:8-25). Although Defendants proposed an incorrect definition, Relator tendered a request that would have properly instructed the jury about this term in accordance with applicable law. The Court overruled Relator's (and Defendants') requests. (04/06/2016 Tr. at 240:4-5, 249:20-21).

As the Court recognized in other instructions, the "reasonable and necessary" requirement governs local contractors in making coverage decisions. (Dkt. 820 at 7-8). "Rather than create distinct criteria for individual claim determinations and LCDs, the Secretary has directed contractors to apply a uniform set of standards, providing that '[w]hen making individual claim determinations, ... [a] service may be covered by a contractor if it meets all of the conditions listed in [MPIM] § [1]3.5.1, Reasonable and Necessary Provisions in LCDs below.'" *Almy v. Sebelius*, 679 F.3d 297, 300 (4th Cir. 2012) (quoting MPIM § 13.3). The legal definition of "reasonable and necessary" in this context is that an item or service is: (1) safe and effective; (2) not experimental or investigational; and (3) appropriate. *Medicare Program Integrity Manual* § 13.5.1. The third element (appropriateness) was not at issue in this case, but if an item or service failed to meet the first or second element, it would not be "reasonable and necessary," *i.e.*, eligible for payment under Medicare. *See id.*; *see also In the Case of D.D.H.*, 2013 WL 8812385, at *5 (Medicare App. Aug. 23, 2013)("if there is not NCD or LCD (as in this case), then there must be published authoritative evidence derived from definitive randomized clinical studies or other definitive studies, **and** general acceptance by the medical community (standards of practice) supported by sound medical evidence based on scientific data or research studies in published, peer-reviewed medical journals, consensus of expert medical opinion, or medical opinion derived from consultations with medical

associationsor other health care experts.") The instruction Relator requested would have instructed the jury on these very points. (Dkt. 801 at 52).

The Court correctly instructed the jury that local contractors are bound by the statutory standard that no payment may be made for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis of illness or injury, but then failed to define the technical term "reasonable and necessary." The failure to properly instruct the jury on the legal meaning of "reasonable and necessary" resulted in a charge that did not "fairly and adequately cover the issues presented." *McDonald*, 674 F.2d at 1089. The jury's verdict cannot stand, and Relator is entitled to a new trial. *See id.*

Moreover, a "statute charged to be violated might easily be subject to misconstruction by the jury unless its provisions were explained by the court." *Schmeller v. U.S.*, 143 F.2d 544, 551 (6th Cir. 1944). Due to the omission of any instruction on the legal standard applicable to the phrase "reasonable and necessary," Defendants' counsel was able to argue in closing that, contrary to the law, the term reasonable allowed the jury to consider "standard of care treatment" and "necessary" "just means that the patient needed the stent." (04/07/16 Tr. at 90:1-9). Defendants' counsel also told the jury that "[e]very doctor testified that biliary stents, including Guidant's stents, were reasonable, necessary, safe and effective and the standard of care." (*Id.* at 111:13-15). These arguments led the jury to misconstrue the statutory requirements and apply a standard that is vastly different than the standard imposed by applicable law. *See Medicare Program Integrity Manual* § 13.5.1. The failure to provide the proper legal definition of "reasonable and necessary" in the charge affected Relator's substantial rights. For the reasons set forth above in this section, and in the interest of justice, a new trial should be granted.

b. *Omitted Instruction on Failure to Disclose*

Relator requested that the definition of "false" in the Court's charge include the instruction that "[a] claim, statement, or record may be false . . . by the failure to disclose facts without which the claim may be considered misleading." (Dkt. 801 at 47 (emphasis added)); 04/06/2016 Tr. at 227:11-24). The Court overruled Relator's request and rejected the tendered instruction. (04/06/2016 Tr. at 240:4-5; Dkt. 820 at 6).

Under the False Claims Act, false claims include not only affirmative misrepresentations but also nondisclosures of fact. *See, e.g., Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999); *United States ex rel. Fry v. Guidant Corp.*, No. 3:03-0842.2006, WL 2633740, at *10-11 (M.D. Tenn. Sept. 3, 2006); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 43 (D. Mass. 2000); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995); *see also Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 127-130 (2003). The Court's instruction on the definition of "false" gave a misleading impression and incomplete (*i.e.*, incorrect) explanation of the law and the issues to be resolved.

c. Omitted Instruction that Government Knowledge is not a Defense to Liability

The Court's charge failed to include any instruction that the government's knowledge regarding claims is not a defense to False Claims Act liability. The Court overruled Relator's objections to the omission and his proposed language that would have properly instructed the jury. (Dkt. 801 at 45; 04/06/2016 Tr. at 226:10-22, 240:4-5).

Defendants' counsel argued in closing that the FDA approved "hundreds of biliary stents" "with full belief that they were being used off-label" and that CMS knew that doctors were using biliary stents in vascular procedures. (04/07/16 Tr. 116:21-117:10; *see also, e.g., id.* at 87:14-23). Further, Defendants introduced extensive hearsay evidence regarding the government's purported knowledge of the Defendants' conduct and the false claims at issue in this case. (*See, e.g.*, 03/29/16

Tr. at 149:10-13; 04/04/16 Tr. at 81:19-82:7, 83:21-84:7, 84:25-85:3, 85:6-9, 86:14-18, 89:2-4, 89:12-13, 91:24-25, 93:21-25, 159:5-6, 159:18-22, 164:4-8, 180:11-14, 185:13-18).

However, under the False Claims Act, the government's knowledge, action, or inaction regarding submitted claims does not alleviate a defendant's liability. *See, e.g.*, *Bollinger*, 775 F.3d at 264; *United States v. Southland Mgmt. Corp.*, 288 F.3d 665, 686 (5th Cir. 2002), *on reh'g en banc*, 326 F.3d 669 (5th Cir. 2003); *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 513 F. Supp. 2d 866, 883 (S.D. Tex. 2007) (citing *United States ex rel. Barrett v. Johnson Controls, Inc.*, 2003 U.S. Dist. LEXIS 5973 at * 37 (N.D. Tex. Apr. 9, 2003)).

The government's knowledge is only relevant (if at all) in evaluating *Abbott's* knowledge for scienter purposes. *Bollinger*, 775 F.3d at 264; *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 952-53 (10th Cir. 2008) (citing *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 & n. 8, 9 (5th Cir. 2003) (en banc) (Jones, J., concurring)); *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1156 (2d Cir. 1993); *Shaw v. AAAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 534 (10th Cir. 2000); *see also United States ex rel. Dekort v. Integrated Coast Guard Sys.*, 705 F. Supp. 2d 519, 543 (N.D. Tex. 2010).

Without Relator's requested instruction, the jury was erroneously allowed to conclude that Defendants were not liable under the False Claims Act because CMS paid claims knowing that vascular procedures were being performed using biliary stents. The absence of the instruction rendered the Court's charge on other applicable standards misleading and provided an incomplete (*i.e.*, incorrect) explanation of the law on Relator's presentment claim.

d. Omitted Instruction that Government Payment is not a Defense to Liability

The Court's charge omitted an instruction that government payment of claims is not a defense to False Claims Act liability. The Court overruled Relator's objections to the omission

and his proposed language that would have properly instructed the jury. (Dkt. 801 at 77; 04/06/2016 Tr. at 226:25-227:10, 240:4-5). Relator has shown above in Section IV(A)(1) how Defendants were able to capitalize on the exclusion of Relator's proffered FDA-related evidence to mislead the jury to believe that the FDA not only knew of, but "blessed," Defendants' conduct. For instance, Defendants argued in closing that CMS continued to pay claims for vascular stenting procedures even though it knew biliary stents were being used and did nothing to eliminate or prevent those payments. (*See, e.g.*, 04/07/16 Tr. at 100:20-101:18). Yet, the government's payment of a claim does not obviate a defendant's False Claims Act liability. *See, e.g.*, *Office of Personnel Mgmt. v. Richmond*, 496 U.S. 414, 427 (1990); *Heckler v. Cmty. Health Servs.*, 467 U.S. 51, 63 (1984); *Utah Power & Light Co. v. United States*, 243 U.S. 389, 409 (1917).

Without the requested instruction, the jury was erroneously allowed to conclude that Defendants were not liable because CMS continued to pay for claims submitted on vascular procedures using biliary stents. The absence of an instruction regarding the government's payment of claims rendered the Court's charge on other applicable standards misleading and provided an incomplete (*i.e.*, incorrect) of the law on Relator's presentment claim.

D. RELATOR DID NOT HAVE A REASONABLE OPPORTUNITY TO MAKE A FULL AND FAIR PRESENTATION OF HIS CASE, WHICH SUPPORTS A NEW TRIAL

"[A] motion for a new trial must be granted if the trial was not fair to the moving party." *Rivas v. Brattesani*, 94 F.3d 802, 807 (2d Cir. 1996) (citing *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1940)); *see, e.g.*, *Smith v. Transworld Drilling Co.*, 773 F.2d 610, 613 (5th Cir. 1985) (new trial is appropriate if "the trial was unfair, or prejudicial error was committed in its course"). The court should evaluate whether, in light of the record as a whole, the moving party was deprived of a fair trial. *See, e.g.*, *Newman v. A.E. Staley Mfg. Co.*, 648 F.2d 330, 334-35 (5th Cir. 1981).

In this case, Defendants were allowed to present extensive evidence that the FDA knew of and approved, and even blessed, Defendants' course of conduct. However, due to the Court's rulings, Relator was unable to present proof to rebut Defendants' evidence.

Defendants capitalized on the Court's evidentiary ruling and errors in the jury charge to give the false impression in closing argument that: (1) the federal government was aware of Defendants' conduct and condoned it; and (2) Guidant's biliary stents must be eligible for Medicare coverage in every contractor jurisdiction and under every LCD simply because of the widespread use of biliary stents in vascular procedures. These arguments prevented Relator from a fair trial of the facts at issue in this case.

E. THE COURT SHOULD GRANT A NEW TRIAL IN THE INTEREST OF JUSTICE

A district court has discretion to grant a new trial to avoid injustice. *See, e.g., Government Fin. Servs. One L.P.*, 62 F.3d at 774; *see also* Fed. R. Civ. P. 61. Each of the reasons discussed above (whether taken individually or considered as a whole) requires the granting of a new trial in the interest of justice.

The Court previously found Relator was not an original source of his fraudulent inducement liability theory and dismissed those claims without giving him the opportunity to present evidence otherwise. (Dkt. 160). At trial Colquitt testified about the training he received on Guidant's products, that Guidant sold its biliary stents exclusively for vascular purposes, and that a marketing manager instructed the national sales force to sell the Omnilink stent for vascular purposes despite the FDA warning label at a meeting before the device was released onto the market. (*See, e.g.*, 03/25/16 Tr. at 44:4-17, 45:12-46, 48:15-51:2, 55:12-56:96). This testimony demonstrates that Colquitt has direct and independent knowledge of Guidant's stent sizes (which the Court found publically disclosed the fraudulent inducement claims) and that Guidant intended its stents solely for vascular use, even before they were brought onto the market, confirms

Colquitt's earlier-established status as an original source. Yet, the claims' dismissal allowed Defendants to argue in closing, without worrying the jury would find fraudulent inducement, that Guidant's biliary stents were designed for vascular use from the outset. (04/07/16 Tr. 120:18-122:24).

Further, the Court previously dismissed Relator's claims outside the time period of his employment. (Dkt. 313). This dismissal hindered Relator's ability to introduce evidence to rebut Defendants' false narratives, for example: that the FDA took enforcement action against Defendants after he blew the whistle, that the FDA instructed the Defendants to communicate to their customers that their biliary stents were not established as safe and effective in vascular procedures, that Defendants deliberately avoided complying with the FDAs instructions, and the Defendants misrepresented to the FDA its compliance. (*See* Dkt. 280-1 at 10-12, 17, 20; Dkt. 785; Dkt. 809). It is contrary to the interest of justice to permit Defendants to evade accountability by making arguments that it defrauded the FDA and by arguing the government was fully aware of condoned Defendants' actions when evidence indicates otherwise.

F. RELATOR IS ENTITLED TO A NEW TRIAL BASED ON VARIOUS ERRONEOUS LEGAL RULINGS MADE BY THE COURT BEFORE AND DURING TRIAL

The Court made a number of rulings averse to Relator as a matter of law. In papers filed with the Court and on the record during hearings and trial, Relator has provided the Court with grounds, authority, and argument demonstrating the error of these rulings. The erroneous rulings include, but are not limited to the Court's adverse pretrial rulings dismissing Relator's fraudulent inducement liability theory and the portions of his claims falling outside the time period of his employment, and the Court's adverse directed verdict against Relator's false statement claim. As discussed above, in Relator's previous filings, and on the record at hearings and trial, these erroneous rulings affected Relator's substantive rights. For those reasons, and in the interest of

justice, Relator is entitled to a new trial so that these issues may be presented to a jury based on a proper record for determination.

Relator incorporates by reference all objections made at trial, all offers of proof made during trial, and all jury charge objections made and instructions tendered during trial. Relator further incorporates all of his prior substantive motions and briefing, including:

Dkt. Nos. 120, 146, 150, 155-56, 158, 161, 165, 170-171, 190, 205, 215, 279-80, 283, 333-34, 352-53, 381-82, 387, 389, 405-6, 443-47, 454-55, 462-63, 459-60, 471, 475, 488-91, 494-95, 501-02, 517-22, 526-30, 538-49, 552-54, 557-59, 591-93, 589-90, 618, 630, 638, 640, 645-50, 663-64, 673, 683, 688-90, 694, 701-13, 716-17, 723, 731, 746-47, 751, 753, 760-61, 768-72, 782-83, 785, 789, 795, 797, 801-02, 808-09.

Relator reserves all of his arguments, objections, requests, and tenders made in and through these incorporated items, each of which (in addition to the arguments made in this motion) supports the granting of a new trial. *See Floyd v. Laws*, 929 F.2d 1390, 1400-1 (9th Cir. 1991) (regarding preservation of error); *accord Richardson v. Oldham*, 12 F.3d 1373, 1377 (5th Cir. 1994); *Sherrill v. Royal Indus.*, 526 F.2d 507, 509 n.2 (8th Cir. 1975); Wright & Miller, *Fed. Prac. & Proc.* § 2818 (3d ed. 2006).

V. REQUEST FOR RELIEF

WHEREFORE, Relator respectfully requests that the Court vacate the April 8, 2016 Final Judgment and order a new trial and for such other and further relief to which he may be justly entitled.

Dated: May 6, 2016

Respectfully submitted,

/s/ Christopher S. Hamilton

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CERTIFICATE OF SERVICE

On May 6, 2016, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served counsel of record in this action electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Christopher S. Hamilton

Christopher S. Hamilton